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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,124	01/12/2004	Andrew L. Abrams	MICRODOSE 99.02 CON2	3144
27667	7590	08/29/2006	EXAMINER	
HAYES, SOLOWAY P.C. 3450 E. SUNRISE DRIVE, SUITE 140 TUCSON, AZ 85718			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/756,124	ABRAMS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan T. Tran	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,3-12,17 and 21 is/are rejected.
- 7) ☒ Claim(s) 13-16 and 18-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The indicated allowability of claims 4 and 5 are withdrawn in view of the newly discovered references to Mladozeniec et al. 4,069,084 and Pletcher et al. US 6,074,688. Rejections based on the newly cited references are as follow.

#### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mladozeniec et al. US 4,069,084.

Mladozeniec discloses a novel dosage form comprising an edible web having deposited thereon a particulate medicament or mixture of incompatible medicaments alternatively between sheets (abstract; and column 4, lines 30-62). Medicaments are deposited on the web in dry powder form (columns 15-16). Medicaments are deposited on the web in fixed unit dose (column 4, lines 29-62). The dosage form offers any desired release pattern including sustained release (column 5, lines 5-53).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al. US 4,069,084, in view Pletcher et al. 6,074,688.

Mlodozeniec is relied upon for the reason stated above. Mlodozeniec does not expressly teach formulating the web into tablet or capsule.

Pletcher teaches a composition comprising a substrate having deposited thereon a specific quantity of dry powder, the substrate being thereafter fabricated to tablet or capsule (abstract; and column 5, lines 5-52).

Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al. US 4,069,084, in view Lerner et al. US 6,197,331.

Mlodozeniec is relied upon for the reasons stated above. Mlodozeniec does not explicitly teach an adhesive on an outer surface of the membrane.

Lerner teaches an oral patch composition comprising drug-containing layer, and an adhesive layer (abstract; and column 9, lines 12-67). Lerner further teaches the patch contains multilayer of different drug (column 10, lines 1-16). Thus, it would have been obvious to one of ordinary skill in the art to modify the novel dosage form of Mlodozeniec to contain an adhesive layer in view of the teaching of Lerner, because the use of a patch that contains layers of premeasured dose of drugs, because Lerner teaches the use drug loaded sheets for controlled release of drugs, and because Mlodozeniec teaches a drug loaded web that is advantageous for a wide variety of controlled release oral dosage forms.

Claims 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al. US 4,069,084, in view of Sanso US 6,350,468.

Mlodozeniec is relied upon for the reasons stated above. Mlodozeniec does not teach the combination of drugs in claims 17 and 21.

Sanso teaches a single unit dosage form comprising two different active ingredients being separated from one another by a membrane (see abstract). Combinations of active ingredients include omeprazole and clarithromycin (column 2, lines 15-32; and claims). Thus, it would have been obvious to one of ordinary skill in the art to modify the dosage form of Mlodozeniec for the combination of omeprazole and clarithromycin to obtain the claimed invention, because Mlodozeniec teaches a novel dosage form for a wide variety of drugs, because Mlodozeniec teaches a novel dosage form that is suitable for combination of two or more incompatible drugs, and because Sanso teaches combination of omeprazole and clarithromycin that is useful in pharmaceutical art.

Claims 1 and 3-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturzenegger et al. US 4,197,289, in view of Mlodozeniec et al. US 4,069,084.

Sturzenegger teaches a sustained release pharmaceutical dosage form comprising edible web having two or more medicaments electrostatically deposited onto the web that is self destructs or degradable in body fluids or enzymes (see abstract, columns 6-8, and columns 24-26). Before the deposit of the medicaments, the web can be coated with an adhesive layer (column 17, lines 5-41). The web can be processed

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into separate tablet layers, capsules, dragees, or suppositories (column 3, lines 38-41; and column 4, lines 58-60).

Sturzenegger does not expressly teach the fixed unit dose quantities of the medicaments.

Mlodozeniec teaches a novel dosage form comprising an edible web having deposited thereon a particulate medicament or mixture of incompatible medicaments alternatively between sheets (abstract, and column 4, lines 30-62). Medicaments are deposited on the web in dry powder form (columns 15-16). Medicaments are deposited on the web in fixed unit dose (column 4, lines 29-62). The dosage form offers any desired release pattern including sustained release (column 5, lines 5-53). Thus, it would have been obvious for one of ordinary skill in the art to modify the dosage form of Sturzenegger to contain a fixed unit dose of drugs in view of the teaching of Mlodozeniec, because Sturzenegger teaches the exact and uniform deposition of the active ingredient on the web (column 11, lines 1-5), because Sturzenegger teaches the amount of active ingredient loaded can be determined by transmission spectrophotometry (column 12, lines 46-56), and because Sturzenegger teaches the advantageous results of a single dosage form containing two or more medicaments being separated by edible membrane, and because Mlodozeniec teaches a novel dosage form containing edible web having deposited thereon a fixed dose of active ingredients that exhibits many advantageous results over the conventional dosage forms (columns 3-4).

***Claims Allowable***

Claims 13-16 and 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', with a large, sweeping loop at the end.

S. Tran  
Patent Examiner  
Art Unit 1615